Citation:

Clifton PM, Noakes M, Keogh JB. Very low-fat (12%) and high monounsaturated fat (35%) diets do not differentially affect abdominal fat loss in overweight, nondiabetic women. *J Nutr.* 2004 Jul; 134 (7): 1,741-1,745.

PubMed ID: 15226463

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine the effects on body fat distribution, weight and lipid profile of consuming either a high monounsaturated fat diet (HIMO) or a very-low-fat diet (VLF) in non-diabetic women.

Inclusion Criteria:

Women with body mass index (BMI) higher than 27kg/m^2 without diabetes (fasting glucose lower than 7.0mmol per L).

Exclusion Criteria:

- Presence of liver or renal disease
- Taking medications likely to affect lipid metabolism
- Consumption of more than 40g ethanol per day.

Description of Study Protocol:

Recruitment

Subjects were recruited using public advertisement.

Design

12-week randomized, controlled, parallel design study.

Dietary Intake/Dietary Assessment Methodology

Subjects completed three-day food records every two weeks.

Intervention

- Women were matched by BMI and age, blocked into two groups and randomly assigned to one of 26,000kJ diets
- The high monounsaturated diet (HIMO) consisted of 35% energy from fat, 20% energy from monounsaturated fat, 6% energy from saturated fat and 21% energy from protein
- The very-low-fat diet (VLF) consisted of 12% energy from fat, 4% energy as monounsaturated fat, 4% energy from saturated fat, and 21% energy from protein.

Statistical Analysis

- Repeated-measures ANOVA was performed taking time as the within-subjects factor and diet as the between-subjects factor
- If the diet X time interaction was significant, a comparison of diets at each time point was carried out
- The data were also analyzed to detect end-point changes by diet and menopausal status using a two-way ANOVA with weight change as a covariate
- Differences were considered significant at $P<0.05$.

Data Collection Summary:

Timing of Measurements

- Subjects followed the intervention diets for 12 weeks
- Subjects were interviewed by a dietitian and completed a three-day food records every two weeks
- Blood samples were taken from fasting subjects, weight was measured and blood pressure was assessed on two consecutive days at weeks zero, four, eight and 12
- Subjects' body fat distribution was assessed at week zero and 12 using dual energy X-ray absorptiometry (DEXA). Waist and hip measurements were taken at these time points as well.

Dependent Variables

- Blood pressure and weight, waist and hip circumference were measured by study personnel
- Lipid profile and blood glucose was assessed using fasting blood draws
- Body fat distribution was assessed using DEXA.

Independent Variables

Dietary intake was assessed using three-day food records.

Control Variables

- BMI
- Age
- Menopausal status.

Description of Actual Data Sample:

- *Initial N:* 70
- *Attrition (final N):* 62 (eight subjects, four from each dietary intervention, withdrew because of inability to maintain compliance or because of work or travel commitments)
- *Subject Characteristics:*

	VLF	HIMO
N	31	31
Age, year	46.9±9.9	47.1±10.7
Waist:hip ratio	34.7±4.3	35.0±3.9
SBP, mmHg	131.0±17.0	132.0±16.5
DBP, mmHg	76.0±10.1	75.6±10.3
Pre-menopausal, N	20	18
Post-menopausal, N	11	13

- *Location:* Australia.

Summary of Results:

Macronutrient and Fatty Acid Intakes

Total fat, carbohydrate, saturated fat (SFA), monounsaturated fat (MUFA) and polyunsaturated fat (PUFA) intakes differed between the groups (P<0.01). Energy intake did not differ.

Diet	Energy, kJ	Protein, %	Fat, %	Carbohydrate, %	Fiber, g	Cholesterol, mg per mJ	SFA, %	MUFA, %	PUFA, %
VLF	6,004±230	21.7±1.1	11.6±1.2	65.4±1.8	31.2±2.6	22.6±4.2	4.1±0.6	3.7±0.6	2.1±0.2
HIMO	5,972±311	21.3±0.9	35.3±1.4	43.7±1.3	32.0±2.7	22.8±4.7	6.4±0.6	19.9±0.8	6.6±0.3

Change in Weight and Body Composition

- Weight loss did not differ between the groups (9.5±2.4 vs. 9.4±3.4kg), nor did total fat loss (6.1±2.4 vs. 6.3±2.7kg), VLF vs. HIMO, respectively
- Total fat mass fell 14% in both groups, from 42.3±11.2 to 36.2±10.2kg in VLF subjects and from 44.1±8.5 to 37.9±8.0kg in HIMO subjects (P<0.01)
- Waist circumference decreased with no effect of diet from 101.2±9.0 to 94.5±9.0 in VLF subjects and from 102.1±9.2 to 95.4±8.5 in HIMO subjects (P<0.001)
- Post-menopausal women lost more abdominal fat and trunk fat than pre-menopausal women (P<0.05) and pre-menopausal women following the HIMO diet had a lower loss of lean mass than those on the VLF diet (P=0.006). The contrast between pre- and post-menopausal women consuming the HIMO diet was also significant (P=0.035).

Change in Blood Parameters

- Total cholesterol fell by more (0.82±0.50mmol per L) in the VLF group than the HIMO group (0.50±0.47mmol per L) in the HIMO group (P<0.0001 time, P<0.05 for the diet effect)
- HDL cholesterol fell by more (0.18±0.23mmol per L) in the VLF group than the HIMO group (0.04±0.19mmol per L) in the HIMO group (P<0.01 time, P<0.01 for the diet effect)
- The change in LDL cholesterol, triglycerides, HDL/LDL ratio and blood glucose did not differ between the diet groups
- Blood pressure declined to the same extent in both groups.

Author Conclusion:

- Weight, total fat mass and regional fat mass loss did not differ between the diet groups, but there was an apparent preservation of lean mass in pre-menopausal women consuming a high-monounsaturated fat diet
- The very-low-fat diet resulted in significantly greater reductions in total cholesterol and HDL compared to the high-monounsaturated fat diet
- The two diets had similar effects on LDL cholesterol, triglycerides, HDL/LDL ratio, blood glucose and blood pressure.

Reviewer Comments:

- *This study followed a small number of subjects (N=31 per diet group)*
- *This study did not report on potential confounding factors that could have affected results, such as physical activity*.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes

3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes

4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	N/A
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	???
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	N/A
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes

	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	No
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes